



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,831	02/04/2002	Michael E. Placke	22000(1)9711CON3	6063

7590

04/27/2004

Steven J Goldstein  
Frost Brown Todd LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, OH 45202

EXAMINER
----------

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/066,831

Applicant(s)

PLACKE ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 24 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 128-150 is/are pending in the application.
- 4a) Of the above claim(s) 132-134, 138-145 and 149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 128-130, 135-137, 146-148 and 150 is/are rejected.
- 7) ☐ Claim(s) 131 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's arguments filed 2/10/04 have been fully considered but they are not persuasive. See arguments below.

I. Rejection of claims 130, 137 under 35 USC 112, 2<sup>nd</sup> paragraph will not be maintained in light of amendment filed 2/10/04. Dependency of claim 130 has been amended to depend from claim 129. The term "anthracycline" is deleted from claim 137.

II. Rejection of claims 128-130, 135, 136, 150 under 35 USC 102(e) as being anticipated by Kaufman will be maintained for reason on record and reason as follows. Applicant argues that Kaufman does not teach that doxorubin liquid dispersions are aerosols or that doxorubin can be delivered as an aerosol via inhalation. Examiner argues that Kaufman clearly states that his drug composition can be delivered to the lungs as a breathable (inhalation) gas (aerosol). See abstract, claims 11 and 12.

III. Rejection of claims 146-148 under 35 USC 103(a) as being obvious over Kaufman will be maintained in light of amendment filed 2/10/04. See Applicant's argument and Examiner's response in II above.

IV. Double Patenting Rejection is maintained over USAN's 09' 677 and 09 '680 now USPN's 6419901 and 6348209, respectively. Based on the Final claims in the USPN's, the status of the Double Patenting Rejection is Statutory.

V. Double Patenting Rejection will not be maintained over USAN's 09 '775, '915, and '345 now USPN's 6471943, 6451784, and 6419900, respectively. The final claims in the USPN's are to a different invention from what is claimed in instant application.

***Claim Objection / Allowable Subject Matter***

Claim 131 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant method of treating cancer by inhaling dactinomycin (electet), mechlorethamine, mitomycin-c or mithramycin.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

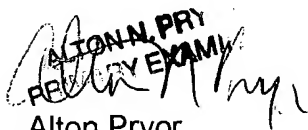
***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

  
ALTON N. PRYOR  
PRIMARY EXAMINER  
AU 1616